Supreme Court, U.S.
FILED

(1) 96 761 NOV 14 1996

OFFICE OF THE CLERK

No. 96-

IN THE

Supreme Court of the United States

October Term, 1996

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,

Cross-Petitioner,

v.

BRACCO DIAGNOSTICS INC., and BRACCO INTERNATIONAL B.V., ORGANON, INC., MERCK & CO., INC., MSD TECHNOLOGY, L.P., SCHERING CORPORATION, HOFFMAN-LA ROCHE, INC., and SYNTEX (U.S.A.), INC.,

Cross-Respondents,

and

DAVID A. KESSLER, M.D., Commissioner of Food and Drugs, and BRUCE A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks

Cross-Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

James F. Flug
Counsel of Record
Reuben B. Robertson, III
INGERSOLL AND BLOCH
1401 Sixteenth St., N.W.
Washington, DC 20036
(202) 232-1015
Attorneys for Cross-Petitioner

CASILLAS PRESS, INC., 1717 K STREET, N.W., WASHINGTON, D.C. 20036

18 pp

QUESTION PRESENTED

A drug patent may receive only one extension under the Hatch-Waxman Act, 35 U.S.C. § 156. The extension period is required to be calculated by the Patent and Trademark Office from the "original expiration date" of the patent at the time PTO grants an extension. The extension becomes "part of the original patent." The question presented is whether the court of appeals erred in ruling that § 156 permits a patentee who received such an extension of its patent term before the effective date of the Uruguay Round Agreements Act ("URAA") to take a second Hatch-Waxman extension of a new patent expiration date made available under the URAA?

PARTIES AND RULE 29.6 STATEMENT

All parties in the consolidated appeal proceedings before the Federal Circuit are listed in the caption.

Cross-Petitioner Generic Pharmaceutical Industry Association is a New York not-for-profit corporation. It has no parent companies, subsidiaries or affiliates. The following firms are members, associate members and affiliate members of the association: A.L. Pharma Inc., Apothecon, Barr Laboratories, Clonmel Healthcare Ltd., Copley Pharmaceutical, Inc., Creighton Products Corporation, Endo Laboratories L.L.C., ESI Lederle Generics, Geneva Pharmaceuticals, Inc., Global Pharmaceutical Corporation, Zenith Goldline, Hoechst Celanese Corporation, Lemmon Company, Perrigo Company, Rosemont Pharmaceutical Corporation, Hoechst Marion Roussel, Inc., Schein Pharmaceutical, Inc., Warner Chilcott Laboratories, Warrick Pharmaceuticals, ACIC Limited, Agvar Chemicals, Inc., Aesgen, Inc., Darby Group Companies, Inc., GYMA Laboratories of America, HMS Sales & Marketing, Inc., Interchem Corporation, KRKA, Lek USA, Inc., Pharma-Kinetics Laboratories, Phoenix International Life Sciences, PLIVA USA INC., Ranbaxy Pharmaceuticals, Inc., Ren-Pharm International, Ltd., Century Financial Services, Inc., Newport Data Associates, Inc., ScinoPharm International, Ltd., CCL Label, Intercall, Inc., and MIM Promark Holdings.

TABLE OF CONTENTS

Question Presented i
Parties and Rule 29.6 Statement ii
Table of Contents iii
Table of Authorities iv
Conditional Cross-Petition 1
Opinions Below 1
Jurisdiction 2
Statutory Provisions Involved 2
Statement of the Case 2
Reasons for Granting the Cross-Petition 7
Conclusion 13

TABLE OF AUTHORITIES

Cases

Merck & Co. v. Kessler, 80 F.3d 1543 (Fed.Cir. 1996) . . . . . *passim*

Merck & Co. v. Kessler, 903 F.Supp. 964 (E.D. Va. 1995) 1

Statutes, Rules and Regulations

28 U.S.C. § 1254(1) 2

35 U.S.C. § 154 . . . . . *passim*

35 U.S.C. § 156 . . . . . *passim*

Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984) . . . . . *passim*

Uruguay Round Agreements Act of 1994 ("URAA"), Pub. L. 103-465, 108 Stat. 4809 (1994) . . . . . *passim*

37 C.F.R. § 1.775 3

Rule 12.5, Supreme Court Rules 2

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

In No. 96-575, Bracco Diagnostics Inc. and Bracco International B.V. (collectively, "Bracco") jointly petitioned this Court for a writ of certiorari to review a judgment of the United States Court of Appeals for the Federal Circuit. The Generic Pharmaceutical Industry Association ("GPIA"), one of the respondents in No. 96-575, conditionally cross-petitions for a writ of certiorari to the Federal Circuit to review the same judgment that is the subject of the Bracco petition. If the Court grants the Bracco petition, it should grant GPIA's cross petition as well.[1] The Federal Respondents also filed a conditional cross-petition for a writ of certiorari on November 8, 1996, relating to the same Federal Circuit decision, which was docketed as No. 96-728.

OPINIONS BELOW

The opinion of the Court of Appeals is reported as *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed.Cir. 1996), and is reproduced in the appendix to the Bracco Petition in Docket 96-575 (hereinafter cited as "Pet.App.") at pages 1a-20a. The opinion of the district court, *Merck & Co. v. Kessler*, 903 F.Supp. 964 (E.D. Va. 1995), is reproduced at Pet.App. 23a-28a. The order of the district court on remand, set forth at Pet. App. 29a-34a, is not officially reported.

---

[1]Organon Inc. filed a petition similar to Bracco's in No. 96-562. However, as the Federal Respondents' brief in opposition to that petition pointed out, Organon's patent expired on November 6, 1996, depriving that matter of any live controversy. The Organon petition did not suggest any other fact or circumstance that would prevent its case from having become moot at that time.

JURISDICTION

The Court of Appeals entered its judgment on April 4, 1996 (Pet.App. 21a-22a) and denied all petitions for rehearing on July 12, 1996. (Pet.App. 35a-40a). Bracco's Petition for a writ of certiorari was placed on this Court's docket on October 15, 1996. This conditional cross-petition is timely under Supreme Court Rule 12.5. The Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are 35 U.S.C. § 154, derived from the Uruguay Round Agreements Act of 1994, Pub. L. 103-465, 108 Stat. 4809 (1994) ("URAA"), and 35 U.S.C. § 156, derived from the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984)(the "Hatch-Waxman Act"). These provisions are set out in the appendix to the Bracco Petition, Pet.App. 54a-73a.

STATEMENT OF THE CASE

Most of the facts and proceedings in the case are set forth in the Bracco Petition at pp. 2-6, and in the Counterstatement of the Case in GPIA's brief in opposition to the Bracco Petition, filed in No. 96-575 simultaneously herewith. Additional facts relevant to this conditional cross-petition are as follows:

The position of the Federal Respondents in the courts below was that the phrase "original expiration date" as used in the Hatch-Waxman Act, 35 U.S.C. § 156, had a fixed meaning that remained constant throughout the life of the

patents at issue here — namely the date 17 years from issuance of the original patent, regardless of any change in patent term pursuant to the URAA. GPIA's approach to reconciling Hatch-Waxman and the URAA was slightly different: GPIA stressed the fact that the grant of a Hatch-Waxman extension under § 156 is not self-executing. It occurs as a result of a formal application to and action by the Patent and Trademark Office ("PTO") after a precisely spelled out, multi-step process. Under the statutory requirements, this once-per-patent process takes place shortly after approval by the Food and Drug Administration ("FDA") of the drug covered by the patent, so that all concerned will know promptly what the extended patent term is. To compute the statutorily prescribed length of an extension, while taking account of various mandatory constraints — especially the 14-year limit on total exclusive market life after the date of FDA approval — the statute and regulations explicitly require PTO to determine and utilize the "period remaining in the [patent's] term," 35 U.S.C. § 156(c)(3), *i.e.* the "original term," *see* 37 C.F.R. § 1.775(d)(2), or the "original expiration date," *see* 37 C.F.R. §§ 1.775(d)(5)(i), (d)(6)(i)(A), (d)(6)(ii)(A), ***as of the time PTO grants the extension***. Upon grant of the extension, a certificate of extension is issued by PTO and must be "recorded in the official file of the patent and shall be considered as part of the original patent" according to 35 U.S.C. § 156(e)(1).

Thus, GPIA argued, since each of the patents in this case had received its one-time Hatch-Waxman extension from PTO before the effective date of the URAA, when the expiration date of each patent was 17 years from date of issuance of the patent, the Hatch-Waxman extension was explicitly determined with respect to, and inextricably

attached to, the then-existing patent expiration date and became "part of" that "original" patent. GPIA pointed out that there is simply no provision in § 156 — nor, for that matter, in the URAA transition provision, 35 U.S.C. § 154(c)(1) — for a second calculation or issuance of an extension already granted, or for severing the prior extension from "the original patent" and re-attaching it to a newly established patent expiration date.

The difference between the government's position and the GPIA position did not affect any patent at issue in this case. However, as a theoretical matter, a patent issued before the URAA effective date, but as to which no Hatch-Waxman extension was granted until after that date, would receive different treatment under the two approaches. Under the government's approach, such a patent would have its post-URAA extension attached to its permanent "original" 17-year term, while under the GPIA approach, the post-URAA PTO extension process would, following the regular procedures of § 156, compute the extension with respect to the then applicable 20-year term and automatically attach this initial Hatch-Waxman extension to that term.

The Federal Circuit rejected the government's position that "original expiration date" means an immutable point in time, once a patent is granted. However, in considering GPIA's alternative approach, the court read the GPIA position narrowly, focussing solely on GPIA's point that the 14-year limit would have to be recalculated by PTO if the pre-URAA extensions were severed from the already extended 17-year term and re-attached to the newly established 20-year term:

> GPIA argues for denial of pre-URAA restoration extensions precisely because FDA [*sic*[2]] would have to recalculate the allowable number of days to insure that the 14-year restriction is met. We do not agree with appellants that pre-URAA patentees should be denied restoration extensions for this reason. GPIA's interpretation would treat otherwise equal patents unequally depending on when the patentee applies for and the FDA [*sic*[3]] grants an extension. Correction to fit within the 14-year limitation entails only a purely ministerial task, no more taxing than the recalculation of a new date for a patent extended by URAA alone (that is, without a restoration extension).

Pet.App. 16a.[Footnote omitted.[4]]

The court did not address GPIA's points that Hatch-Waxman extensions are not self-executing, that they are required to be performed by PTO at a specific time, that they require a determination of the "original expiration date" as of

---

[2] Like Bracco, Bracco Pet. p. 4, the Court apparently confused the roles of FDA and PTO in the Hatch-Waxman process. While the FDA (as designee of the Secretary of Health and Human Services) does have a role in reporting the number of days that a drug has spent in the FDA approval process, and in determining due diligence, *see* 35 U.S.C. § 156(d)(2), the ultimate calculation and grant of an extension is committed to the PTO, see 35 U.S.C § 156(e)(1).

[3]See footnote 2. The fact that this error was made twice has serious implications which are discussed below.

[4]The omitted footnote points out that the district court had failed to perform the "purely ministerial task" of computing and applying the 14-year limit applicable to one of the patents at issue.

that time, and, once granted by PTO, that they become part of the "original" patent, *i.e.* the patent in force at the time of PTO's action under § 156.

However, the court did accept, at least in part, three of GPIA's key points:

1. The district court had rejected GPIA's argument that, as to all patents with pre-URAA Hatch-Waxman extensions, the post-URAA act of attaching a (recalculated) Hatch-Waxman extension to the newly established 20-year term would constitute a prohibited second extension. However, the Federal Circuit accepted in principle the general premise of this point. It ruled that, as to those patents which had begun utilizing their pre-URAA § 156 extensions before the URAA effective date — five of the twelve patents at issue in the case — "a reapplication of the restoration extension would constitute a second extension contrary to the statute." Pet.App. 18a. Of course, the reason for this cross-petition is that the Court of Appeals did not apply the same principle to the other seven patents at issue, all of which also had received pre-URAA first extensions.

2. In rejecting the government's position that "original expiration date" forever refers to the 17-year term of pre-URAA patents, the Federal Circuit concluded "that 'original expiration date' means no more than that the expiration date has not been extended under section 156(e)(1) and, thus, the phrase can identify more than one date." Pet.App. at 15a. The court cited as an example the grant of a new type of non-Hatch-Waxman extension under § 154(b)(2), "which would be added to the term *prior* to the addition of a restoration extension which, under section 156(a), is added to the end of what would otherwise be the patent term." This interpreta-

tion, focussing on the status quo ***at the time of the Hatch-Waxman extension***, coincides exactly with the GPIA interpretation; however, as discussed below, the court failed to follow this interpretation to its logical conclusion.

3. Rejecting the idea that it could avoid the excess extension problem for a Bracco-type patent by splitting the extension between the pre-URAA time already used and the time to be added to the URAA, the Court declined "to rewrite the statute." Pet.App. 19a. But again it provided no reasoned explanation of why its retroactive recalculation and reissuance of the seven re-extended patents was not such a rewriting, since neither statute provided for that process or that result.

REASONS FOR GRANTING THE CROSS-PETITION

GPIA's brief in opposition to Bracco's petition for certiorari in No. 96-575 explains why this case does not meet the standards for this Court's review of the issue raised by Bracco, namely the Federal Circuit's denial of a second extension to patents which had begun to utilize their prior Hatch-Waxman extensions before the effective date of the URAA, and why the circuit court decision on that issue was correct.

However, should this Court decide to grant the Bracco Petition and review the decision below on that issue, the Court should also grant this cross-petition in order to consider the Federal Circuit's error in affirming the judgment of the district court with respect to seven of the patents in the

case.[5] That error was the failure to recognize that severance of any pre-URAA Hatch-Waxman extension from the term that it had become "part of," and its recalculation in respect to, and re-attachment to, the subsequently authorized 20-year term, is equally the granting of a prohibited second Hatch-Waxman extension, accomplished without any of the clearly specified and time-limited administrative actions required by Congress, and without any authority in any provision of the two laws at issue, thus constituting a "rewriting" by the court of those laws.

In addressing this case, the Court of Appeals conceded that it was acting on a matter which Congress had not "expressly" addressed in either Hatch-Waxman or the URAA. Pet.App. 8a. It ultimately stated its goal as adopting an interpretation under which "all provisions of both URAA and Hatch-Waxman can reasonably be given effect." *Id.* at 14a. GPIA respectfully submits that, to achieve that goal, the court should have applied to all patents granted extensions before June 8, 1995, the same logic, and same constraints of Hatch-Waxman, as it applied to the patents which happened to begin using their extensions before that date. The court should have drawn its bright line between patents which *received* their Hatch-Waxman extensions before and those which *received* their extensions after the URAA effective date, rather than between those which *began using* their

---

[5]GPIA, as previously indicated, does not consider the Organon petition in No. 96-562 a viable petition since even under the district court's decision, which the Federal Circuit reversed, Organon's patent would now have expired, apparently rendering its claim moot.

extensions before and those which *began using* their extensions after that date.

First, adding pre-URAA Hatch-Waxman extensions onto the end of 20-years-from-date-of-application expiration dates newly granted to patents eligible under the URAA transition clause would fulfill none of the purposes of either law. As the Court of Appeals noted, Pet.App. 7a, the purpose of the URAA was not to extend patents but to conform U.S. patent law to the laws of most other developed nations, which use the 20-years-from-application standard. That goal was met as soon as each patent in force on June 8, 1995, was given the option of applying the 20-year calculation if that would give it a longer life than its pre-existing patent life under the prior law. And no purpose of Hatch-Waxman is served by giving these transitional patents a life longer than the life granted by PTO when their one-time Hatch-Waxman extensions were applied for, calculated, and issued. Those extensions fully provided whatever retroactive or prospective benefit that Congress intended to offer these patentees when, in 1984, it provided for extensions to the 17-year term.

Second, the Court of Appeals decision conflates the mechanism of the URAA transitional provision, which Congress made self-executing so that all existing patents would meet the URAA 20-year standard automatically on the effective date, with the mechanism of Hatch-Waxman, which is not self-executing at all, but requires an elaborate administrative process culminating in PTO's discrete act of granting a § 156 extension. That process takes place only once in time, upon an application by the patentee within 60 days of FDA approval of the patented drug, and explicitly requires the PTO to determine at that time "the period

remaining in the term of [the] patent after [FDA's] approval of the approved product...." *See* §§ 156(d)(1)), 156(c)(3). As the court conceded, neither Hatch-Waxman nor URAA explicitly authorizes or directs any departure from this statutory scheme by PTO, by a court, or by patentee self-certification. The fact that some of PTO's functions may be seen as "ministerial" does not erase the fact that they are Congressionally mandated.

In fact, the court's repeated erroneous reference to FDA (see notes 2 & 3, *supra*) as the source of the calculation and grant of a Hatch-Waxman extension suggests that it may not have sufficiently focussed on the details of the PTO's Hatch-Waxman responsibilities, and thus may not have fully appreciated the non-self-executing nature of this process. On the other hand, the court did recognize, in rejecting the government's "fixed original expiration date" approach, that the § 156 process would now have to take into account the new non-Hatch-Waxman extensions before adding on the Hatch-Waxman time. But that logic suggests that in every case the term extended by PTO under Hatch-Waxman must be the term in existence at the time the one-time statutory Hatch-Waxman process is completed, which for these patents was prior to the URAA effective date, when the only patent term to which the extensions could be added was the 17-year term. If this Court addresses these issues, it should apply that logic.

Third, the Court's complaint that "GPIA's interpretation would treat otherwise equal patents unequally depending on when the patentee applies for and the FDA [*sic*] grants an extension" (Pet.App. 16a) is not persuasive in the context of two statutes rife with arbitrarily drawn bright lines, which

drastically change the outcome for particular patents which may have only a day's difference in their chronology. For example, Hatch-Waxman limits extensions on certain patents to two years and others to five years, depending on whether or not the patent was issued, or other actions occurred, before or after the date of enactment of Hatch-Waxman. *See* § 156(g)(6). And URAA limits transitional treatment to those patents applied for or granted before June 8, 1995. *See* § 154(c)(1). A patent applied for on June 9, 1995, will receive ***only*** the 20-years-from-application term, even if the 17-year-from-issuance term would have been longer. Similarly, a patent which expired on June 7, 1995, the day before URAA took effect, was lost forever, even if 20 years from its date of issue would have been well after June 7, 1995; but a patent which under previous law would have expired on June 9, 1995, will be extended to the 20-year-from-date-of-application expiration date if that date is later than June 9, 1995. Surely GPIA's conclusion, that § 156 defines a Hatch-Waxman extension as of the date it is granted, establishes a bright line that is no more arbitrary, and probably more fair, than the other bright lines found in these statutes.

Fourth, the court correctly concluded that the belated addition of a further extension to the URAA term of a patent in force on June 8, 1995, only because of its previous Hatch-Waxman extension would constitute a prohibited second Hatch-Waxman extension. But if this is so as to those patents, it should also be so as to all patents with pre-URAA § 156 extensions, which pursuant to the statute became an integral "part of" those patents. The fact that they had not begun to utilize the extended portion of those terms should not be determinative, because they eventually receive the full benefit

of the extended 17-year term if that term is better for them than the transitional URAA 20-year term.

In short, contrary to its stated intention, the Court of Appeals did rewrite the statute, and it did so in a manner that unnecessarily conflicts with the law as written. Its ruling means that § 156(e)(1) now reads as follows [the imputed new language is shown in italics]:

> ... If the Commissioner [of Patents] determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension ... a certificate of extension ... for the period prescribed by subsection (c), *except that, if this extension has not yet begun to run, and the patentee wants its extension severed from this patent term and recalculated, and re-granted with respect to some new patent term established by Congress, the requirement of subsection (a)(2) that the patent has never before been extended under this subsection shall not apply, and the 14 year limit which PTO is required to calculate may be calculated by the patentee, and the patentee may self-certify its new patent expiration date without action of PTO, without issuance of the required certificate of extension, and without provision for the required recording of the new date in the official file of the patent.*

Perhaps if Congress had been lobbied by the patentees to adopt such an amendment to Hatch-Waxman, it might have done so, despite what would have been the strong opposition of the generic drug industry, and the patient community. But

there is no need to speculate on what might have been: Congress did not do so, and there is no basis for any court to step in to "rewrite the statute" under these circumstances.

GPIA's common-sense reading of the statutes meets all of the purposes of both laws, without running afoul of the language of either. It should be adopted by this Court, if it decides to review the decision of the Court of Appeals.

CONCLUSION

The Court should grant GPIA's conditional cross-petition for a writ of certiorari to the Federal Circuit in the event that it grants the Bracco Petition in No. 96-575.

Respectfully submitted,

JAMES F. FLUG
Counsel of Record
REUBEN B. ROBERTSON, III
INGERSOLL AND BLOCH
1401 16th Street, N.W.
Washington, DC 20036
(202) 232-1015

Attorneys for
Cross-Petitioner
Generic Pharmaceutical
Industry Association

November 14, 1996